DOCKET NO.: VDX-5001USNP

Application No.: 10/781,036

Office Action Dated: May 10, 2006

## Remarks/Argument:

**Description of Amendments to the Claims.** 

Claims 1-6, 8-9, and 11-15 have been cancelled. Accordingly, all rejections to such claims are obviated. Claims 7, 10, 16, and 17 are currently being prosecuted.

Claim 7 has been amended to recite steps involving removing cellular debris and other non-RNA materials from the sample, decanting the supernatant from the container, and extracting RNA from the decanted supernatant. Support for these amendments is found at page 2, lines 9-11 and page 3, lines 5-10 of the application. The claim has also been amended to recite the nature of its contact of the disruption element with the container in which it is employed and with the sample placed in the container. That is, the contact is rolling contact as is the case when, for example, the disruption element is a bead/ball. Support for this amendment is thus found at page 3, line 16.

Claim 16 has been amended to recite that the method of extracting nucleic acids is conducted during the course of a surgical procedure using a sample obtained from the that surgical procedure. Support for this amendment is found at Claim 16 as originally filed in light of its reference to intra-operative assays referred to in page 1, line 27 of the application.

Accordingly, no new matter has been added.

## **Response to Rejections**

Claims 7, 10, 16, and 17 are subject to obviousness rejections over Spelsberg ('846) in view of Gautsch ('501). These rejections are respectfully traversed for the following reasons.

Spelsberg's '846 patent is directed entirely to a continuous flow device that incorporates a pestle that operates in the same manner as a plunger (though it may rotate about the

DOCKET NO.: VDX-5001USNP

Application No.: 10/781,036

Office Action Dated: May 10, 2006

longitudinal axis of the container). The device operates in "continuous flow". That is, sample is extracted through an outlet as it is processed through the device. Col. 2, line 5. Clearly, the sole means for movement of the disrupting element of this device is a member that is fixed to it and which is driven along the length of the longitudinal axis of the container in which it operates. Given the description of the device provided, it is not possible that the disrupting element could be a ball or bead. The pestle engages only in sliding contact with the container in which it is used and is certainly not in rolling contact with the sample. Col. 3, lines 59-63.

The Gautsch '501 patent is directed in its entirety to a device in which disrupting elements are limited to particles and do not include the pestle approach of Spelsberg. Col. 4, lines 34-37. The force used to disrupt cells is said to be attributable to the oscillatory movement of the vessels in which the sample is place rather than the unidirectional movement of a plunger. Col. 5, line 59. The Gautsch device could not be operated in continuous flow since the containers in which the sample is placed are sealed during use. Col. 9, lines 10-15.

All of the Examiner's rejections of the claims left in prosecution depend on the combination of the Gautsch and Spelsberg patents. However, there is no teaching, suggestion or motivation to combine them given the differing mechanisms by which they operate. Indeed, quite the opposite is true. One skilled in the art would not look to do so. There is nothing in either reference to even hint at combining the teachings from the use of a continuous flow, plunger like, device to a batch operated, sealed oscillatory device. Furthermore, the Gautsch patent makes repeated reference to its position in the art as an improvement to bead mills, not driven pestle devices such as that of Spelsberg. Gautsch is thus best seen as teaching away from Spelsberg.

Since there is no teaching, suggestion, or motivation to combine references and because Gautsch actually teaches away from Spelsberg, the references should not be combined in the manner suggested by the Examiner. Accordingly, the rejections are overcome and a

DOCKET NO.: VDX-5001USNP

Application No.: 10/781,036

Office Action Dated: May 10, 2006

timely notice of allowance is respectfully solicited.

Respectfully submitted,

/Todd Volyn/ Todd F. Volyn Reg. No. 37,463

Johnson & Johnson.
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Telephone: 732-524-6202

Dated: June 1, 2006